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WISCONSIN-MADISON
MEDICAL SCHOOL

1427 92 1001-8 10 54

October 26, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Dear Sirs:

After reading the Federal Register on suitability determination for donors of human cellular and tissue-based products, (docket no. 97N-484S), I would like to call your attention to one problematic omission. In your description of tests done for potential semen donors you include CMV serum titers. However, you go on to say that a positive titer should not prevent a candidate from being a donor if they are currently negative for shedding of virii, (active infection). The problem I foresee is that you do not specify a means for assuring that viral shedding is not occurring. It would be most helpful to those involved in this industry if the regulations specified the type of tests that would be used for determining the presence or absence of CMV viral shedding.

Thank you for your attention in this matter.

Sincerely,

Sander S. Shapiro, MD
Professor – Obstetrics and Gynecology
Director, Women's Endocrine Services

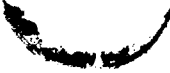
Department of Obstetrics and Gynecology



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